

**Notice of Allowability**

| Application No.    | Applicant(s) |
|--------------------|--------------|
| 09/973,180         | DUIJN ET AL. |
| Examiner           | Art Unit     |
| Jeanine A Goldberg | 1634         |

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 1/29/04.
  2.  The allowed claim(s) is/are 1, 2, 30-32, 39.
  3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
  4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a)  All
    - b)  Some\*
    - c)  None of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with Angela Dai on March 1, 2004.

3. The application has been amended as follows:

A) Claim 30 (Amended) A method for determining whether an individual has an increased risk of developing HH disease comprising:  
obtaining SLC11A3 DNA from the individual and  
assessing the SLC11A3 DNA sequence for the identity of the nucleotide at position 734 (A734C) of SEQ ID NO: 1,  
wherein the presence of the A nucleotide indicates the absence of a HH gene mutation in the genome of the individual and  
wherein the presence of the C nucleotide indicates the presence of the HH gene mutation and an increased risk of developing HH disease in the genome of the individual.

4. The following is an examiner's statement of reasons for allowance.

The drawings have not been entered for the reasons previously of record.

The claims are drawn to a nucleic acid sequence comprising a mutation and a method of determining whether the mutation is present as indicative of an increased risk of developing HH disease.

An isolated nucleic acid of SEQ ID NO: 1 is free of the art. The art does not teach cDNA from the SLC11A3 (SEQ ID NO: 1) containing a mutation in exon 5, position 734 which results in a transversion between an A-C. The instant specification states that "all symptomatic HH patients contain a heterozygous A-to-C transversion at position 734 (A734C) compared to 200 healthy controls (page 25, para 63). The specification states that the base change is the causative mutation for HH.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (571)272-0507

  
Jeanine Goldberg  
Patent Examiner  
March 5, 2004

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600